K113006

MAY 25 2012

510(k) Summary
for the iFUSE Hammertoe System

In accordance with 21 CFR 807.92 of the Federal Code of Regulations the following 510(k) summary is submitted for the iFUSE Hammertoe System

1. GENERAL INFORMATION

Date Prepared: October 3, 2011

Trade Name: iFUSE Hammertoe System

Common Name: screw, fixation, bone

Classification Name: Smooth or threaded metallic bone fixation fastener

Class: II

Product Code: HWC

CFR section: 21 CFR section 888.3040

Device panel: Orthopedic

Legally Marketed Predicate Device: Stayfuse, Pioneer Surgical Technology, K990804
OthoPro Stemman Pins and Kirschner Wires, OrthoPro LLC, K070555

Submitter: OrthPro, LLC
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2. DEVICE DESCRIPTION

The iFUSE Hammertoe System by OrthoPro is a single piece metal implant that is surgically inserted into the intramedullary canal of the bones in the toe, finger or small bones, designed to create a fusion.

Materials: Ti-6AL-4V-ELI per ASTM F136

3. SUBSTANTIAL EQUIVALENCE CLAIMED TO PREDICATE DEVICES

The iFUSE Hammertoe System is substantially equivalent to the predicate device in terms of intended use, design, materials used, mechanical safety and performances.

4. INTENDED USE

The iFuse Hammertoe system is designed for small bone fusion and fractures. It is indicated for fractures, and inter-digital fusion of the fingers, toes and small bones.

5. NON-CLINICAL TEST SUMMARY

The following testing was performed:

- Pullout strength
- Four point bending and fatigue strength

The results of this testing indicate that the iFUSE Hammertoe System is equivalent to predicate devices.

6. CLINICAL TEST SUMMARY

No clinical studies were performed.

7. CONCLUSIONS NONCLINICAL AND CLINICAL

The conclusions drawn from the comparison between the devices demonstrate that the iFUSE Hammertoe System is as safe, as effective, and performs as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OrthoPro LLC
% The OrthoMedix Group, Incorporated
Mr. J.D. Webb
1001 Oakwood Boulevard
Round Rock, Texas 78681

MAY 25 2012

Re: K113006
Trade/Device Name: I-Fuse Hammer Toe Systems
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: April 4, 2012
Received: April 10, 2012

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K113006

Device Name: I-Fuse Hammer Toe System

Indications for Use:

The iFuse Hammertoe system is designed for small bone fusion and fractures. It is indicated for fractures, and inter-digital fusion of the fingers, toes and small bones.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113006